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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROMEO, DAVID S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,016	CELESTE ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0105*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 01/03/2005 has been entered. Claims 25-40 are pending and being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 29-36, 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of promoting neuronal cell survival, does not reasonably provide enablement for a method of inducing neuronal cell differentiation from a progenitor cell or a method of modulating proliferation of neuronal cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue that the examiner has not shown that undue experimentation would be required in order to practice the claimed invention and that the examiner has not provided a reasonable basis to the enablement of the claimed invention. Applicants argue that their evidence outweighs the examiner's evidence. Applicants argue that example 9 discloses assays for promoting neuronal differentiation that were well known in the art an could be applied by a skilled artisan without undue experimentation, that additional guidance is provided on page 18, lines 25-31, and on page 19, liens 23-27. Applicants argue that Gamer (Dev Biol. 1999 Apr

1;208(1):222-32) and Liu (Neuron. 2001 Dec 20;32(6):997-1012) demonstrate that claimed methods of inducing neuronal cell differentiation are enabled.

Applicant's arguments have been fully considered but they are not persuasive.

Prior to 11/07/1997 (the filing date of U. S. Application No. 08/966,297) the disclosure only contemplates that BMP-11 may be useful in promoting neuronal cell survival, referring to Schubert et al., Nature, 344:868-870 (1990). In U. S. Application No. 08/966,297 (filed 11/07/1997) it is disclosed that BMP-11 promotes survival of PC12 cells under serum-free conditions, and that BMP-11 induces neurite formation in PC12 cells. However, claims 29, 30, 35, 36, 38-40 are directed to or encompass inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells. Claims 31-36 are directed to or encompass modulating the proliferation of any and/or all neuronal cells. Applicants rely on Gamer and Liu as further support for enablement of the full scope of the claimed invention. Gamer and Liu obtained their results using embryonic tissue. Gamer's results "suggest that during vertebrate embryogenesis, BMP-11 plays a unique role in patterning both mesodermal and neural tissues" (Abstract). Liu provides evidence that the convergent activities of FGFs, Gdf11, and retinoid signals originating from Hensen's node and paraxial mesoderm establish and refine the Hox-c positional identity of motor neurons in the developing spinal cord (Abstract) in neural explants isolated from chick embryos (page 1010, left column, last full paragraph). However, the cells in an adult are unlike the cells in an embryo because the cells in an embryo are undifferentiated.

Gamer also demonstrates that BMP-11 shares 90% amino acid sequence identity within the carboxyl terminal domain with GDF-8/mytostatin (page 223, right column, last full

paragraph). Although BMP-11 and GDF-8 proteins appear to have similar activities in the Xenopus animal cap assay, the data suggest that BMP-11 and GDF-8 adopted different functions as they evolved from a common ancestral gene (page 231, left column, full paragraph 1).

Liu used the expression profile of Hox-c proteins to define the source and identity of patterning signals that impose motor neuron positional identity along the rostrocaudal axis of the spinal cord (Abstract). However, Liu also discloses that Gdf11 and Gdf8 appear to have little intrinsic Hox-c-inducing activity (paragraph bridging pages 1003-1004).

Jordan clearly states that:

> BMPs 9 and 11 did not promote the in vitro survival of dopaminergic neurons (page 1703, paragraph bridging left and right columns).
>
> BMP-11 had no effect on BrdU incorporation and astroglial cell maturation, indicating that not all members of the BMP family share effects on proliferation and differentiation of cells in the astrocyte lineage (page 1703, right column, full paragraph 1).
>
> BMPs are distinct from each other with regard to their neurotrophic potentials (page 1705, left column, full paragraph 1). The BMPs are heterogeneous with regard to the their biological effects (paragraph bridging pages 1705-1706).

The results seen with embryonic tissue are not predictive of inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or of inducing the modulation of the proliferation of any and/or all neuronal cells, as evidenced by Jordan. Furthermore, embryonic cells are unlike those in the adult because embryonic cells are undifferentiated and the specification lacks guidance for, and working examples of, inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells and modulating the proliferation of any and/or all neuronal cells. The examiner is aware that working examples are not required. However, the lack of working examples is a

factor to be considered. In view of this evidence, Applicants have failed to establish a nexus between "neurite formation" in PC12 cells and the full scope of inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or of modulating the proliferation of any and/or all neuronal cells.

Applicants argue that the full scope of the claimed methods of modulating proliferation of neuronal cells is enabled based on the present disclosure at page 45, lines 8-27, page 45, line 35, to page 46, line 3, and Table II. Applicant's arguments have been fully considered but they are not persuasive. Applicants have not presented any evidence that MTS reduction by cellular NADH and NADPH from living cells (present disclosure at page 45, lines 8-27, page 45, line 35, to page 46, line 3, and Table II) is indicative of increased or decreased cell proliferation. The examiner concludes that Applicants' argument is mere argument. Furthermore, the term "modulating proliferation of neuronal cells" encompasses either increasing or decreasing the proliferation of neuronal cells. The specification has not shown, for example, how to inhibit neuronal cell proliferation in situations where BMP-11 induces neuronal cell proliferation, or how to, for example, induce neuronal cell proliferation in situations where BMP-11 inhibits neuronal cell proliferation.

Applicants argue that based on based on the teachings of Massague (Cell. 1992 Jun 26;69(7):1067-70), that the skilled artisan would not expect the effects of BMP-11 to be identical (or even similar) to those of activin. Applicant's arguments have been fully considered but they are not persuasive. The examiner did not say that activin is the same protein as BMP-11. Nor did the examiner say that the skilled artisan would expect the effects of BMP-11 to be identical (or even similar) to those of activin. The examiner was merely saying that the effects of a

protein, activin, that belongs to the same superfamily of proteins as BMP-11 (Massague (Cell. 1992 Jun 26;69(7):1067-70, page 1067, Figure 1), are neuronal cell type specific, and that the skilled artisan would reasonably not expect any and/or all BMPs, nor any and/or all TGF-β superfamily members, to successfully inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or modulate the proliferation of any and/or all neuronal cells. It is further noted that BMP-11 is more structurally similar to the inhibin class of TGF-β-related proteins because of its cysteine pattern and shows as much sequence identity in the mature region to BMP-2 and -4 as it does to inhibin βa, βb, and βc (Gamer, page 223, right column, last full paragraph). Furthermore, Gamer (Dev Biol. 1999 Apr 1;208(1):222-32) teaches that in Xenopus embryos, BMP-11 acts more like activin, inducing dorsal mesoderm and neural tissue, and less like other family members such as BMPs 2, 4, and 7, which are ventralizing and anti-neuralizing signals (Abstract).

Applicants argue that in spite of Schubert teaching that activin did not increase the survival of ciliary ganglion cells or of several glial cell lines (page 869, right column, last full paragraph), Schubert enables the scope of the presently claimed methods because Schubert shows that activin promotes the survival of P19, B33, and retinal cells, because Schubert concludes that the results show that activin A promotes nerve cell survival, because the title of the Schubert article is "Activin is a nerve cell survival factor." Applicant's arguments have been fully considered but they are not persuasive. Schubert, taken as a whole, teaches that the effects of activin are neuronal cell type specific, and therefore the skilled artisan would reasonably not expect any and/or all BMPs, nor any and/or all TGF-β superfamily members, to successfully

inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or modulate the proliferation of any and/or all neuronal cells.

Applicants argue that a skilled artisan would know how to confirm the operability of the claimed methods using only routine experimentation and well known assays. Applicant's arguments have been fully considered but they are not persuasive. Jordan is evidence that the full scope of the claims is not enabled.

Applicants argue that Jordan does not contradict Applicants' data and that Jordan shows that BMP-11 increases the number of dopaminergic neurons. Applicant's arguments have been fully considered but they are not persuasive. Jordan clearly states that:

> BMPs 9 and 11 did not promote the in vitro survival of dopaminergic neurons (page 1703, paragraph bridging left and right columns).
>
> BMP-11 had no effect on BrdU incorporation and astroglial cell maturation, indicating that not all members of the BMP family share effects on proliferation and differentiation of cells in the astrocyte lineage (page 1703, right column, full paragraph 1).
>
> BMPs are distinct from each other with regard to their neurotrophic potentials (page 1705, left column, full paragraph 1). The BMPs are heterogeneous with regard to the their biological effects (paragraph bridging pages 1705-1706).

Applicants argue that the present claims require the use of a therapeutically effective amount of BMP-11, that Jordan only tests a single dose (10/ng/ml), which a skilled artisan would consider a low dose, as evidenced by Gamer at 226, right column, full paragraph 1, and that the skilled artisan could determine an effective concentration of BMP-11 with only routine experimentation. Applicant's arguments have been fully considered but they are not persuasive. Jordan indicates that the EC_{50} was 2 ng/ml for each BMP, and concentrations of $\geq$ 5 ng/ml were already saturating (page 1703, paragraph bridging left and right columns). Furthermore, Gamer

at page 226, right column, full paragraph 1, teaches that BMP-11 was active at a concentration of 10 ng/ml. The examiner concludes that Applicants' argument is mere argument.

Applicants argue that Jordan's negative results can be explained by a variety of technical considerations and that in Example 9 of the present specification it is shown that BMP-11 exerts an approximately 5-fold effect on the number of viable cells. Applicant's arguments have been fully considered but they are not persuasive. Applicants tested PC12 cells in Example 9. Jordan tested dopaminergic neurons and astroglial cells. The scope of the claims encompasses inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or modulate the proliferation of any and/or all neuronal cells. Jordan is evidence that the full scope of the claims is not enabled. Whether a skilled artisan would give more weight to the present results or Jordan's results is mere argument.

Applicants argue that the heterogeneity between different BMPs is irrelevant to enablement of the claimed invention. Applicant's arguments have been fully considered but they are not persuasive. Applicants are claiming methods utilizing a heterogeneous genus of BMP-11 polypeptides encoded by a genus of nucleotides that hybridize under an undefined set of stringency conditions to SEQ ID NO: 10 and that encode a protein having BMP-11 in an osteoinduction assay. Jordan is evidence that effects of such mutations on neural cells is unpredictable. Applicant has taken the position that 35 U.S.C. § 112, first paragraph, permits an artisan to present claims of essentially limitless breadth so long as the specification provides one with the ability to test any particular embodiment which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those that don't. However, the issue here is the breadth of the claims

in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance provide by the instant specification. The present claims are directed to or encompass inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or modulate the proliferation of any and/or all neuronal cells. The present specification discloses that BMP-11 promotes survival of PC12 cells under serum-free conditions, and that BMP-11 induces neurite formation in PC12 cells. Jordan is evidence that the full scope of the claims is not enabled and that BMPs are distinct from each other with regard to their neurotrophic potentials. The scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification. The examiner is not arguing that BMP-11s from different species are cross-species reactive. In fact, human and mouse BMP-11 share 99.5% identity over the entire amino acid sequence. See Gamer (Dev Biol. 1999 Apr 1;208(1):222-32) page 223, right column, full paragraph 1. The fact that two proteins that share 99.5% identity over the entire amino acid sequence may be cross-species reactive does not enable the full scope of the claimed invention, when the claims are directed to or encompass inducing neuronal cell differentiation from any and/or all progenitor cells, stem cells, neural cells, or neuronal cells or modulate the proliferation of any and/or all neuronal cells, because the evidence shows that results with PC12 cells and embryonic tissues are not predictive of any and/or all neuronal cells.

Double Patenting

Claims 25-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6340668, and, if

necessary, in view of Wozney (A). Applicants statement traversing this rejection and request to hold the rejection in abeyance are acknowledged. Applicants will consider whether to file a terminal disclaimer when allowable subject matter is indicated. However, there are no provisions for holding a rejection in abeyance. It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see 37 CFR 1.116) or reinstate previously canceled claims.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 25-34, 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite over the recitation of "having BMP-11 activity in an osteoinduction assay" because it is unclear what BMP-11 activity is intended. For example, it is unclear if the protein induces or inhibits osteoinduction, neurogenesis, or some other unknown and undescribed activity. The metes and bounds are not clearly set forth.

Claims 25-34, 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25-34, 37-40 are indefinite over the recitation of "stringent conditions" because stringency varies according to the hybridization conditions and the particular hybrid under study.

The specification fails to limit the metes and bounds of "stringent conditions". The metes and bounds are not clearly set forth.

Claims 39, 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 40 are indefinite because "progenitor cell" implies an undifferentiated cell, whereas "neural cell" or "neuronal cell" implies a differentiated cell. It is unclear if a progenitor cell or a differentiated cell is intended. The metes and bounds are not clearly set forth.

Claims 25-34, 37-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising amino acids 7-108 of SEQ ID NO: 11 or amino acids 1-109 of SEQ ID NO: 11, does not reasonably provide enablement for a BMP-11 polypeptide encoded by a nucleotides that hybridize under stringent conditions with nucleotide sequences (i) or (ii) and encode a protein having BMP-11 activity in an osteoinduction assay. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The present claims are directed to or encompass a BMP-11 polypeptide encoded by a nucleotides that hybridize under stringent conditions with nucleotide sequences (i) or (ii) and encode a protein having BMP-11 activity in an osteoinduction assay. It is unclear if the protein induces or inhibits osteoinduction, neurogenesis, or some other unknown and undescribed

activity in an osteoinduction assay. It is noted that nucleic acid sequences that hybridize to (i) or (ii) hybridize to the coding sequence and are antisense to the coding sequence and therefore do not encode anything remotely resembling the exemplified BMP-11, SEQ ID NO: 11. Although the hybridization conditions imply a level of similarity at the nucleotide level, they do not imply like similarity at the amino acid level because of the significant number of amino acid insertions, substitutions, and deletions implied by the hybridization conditions. The instant specification provides no guidance as to which amino acid residues in SEQ ID NO: 11 are essential to the structural and functional integrity of the polypeptide and which are expendable or substitutable. The instant specification provides no working examples and no guidance that would permit an artisan to practice the invention commensurate with the scope of the instant claims.

To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of work or testing in the assays than are described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues in the amino acid sequence of SEQ ID NO: 11 which are required for the functional integrity of that protein. It is this additional characterization of that single disclosed, naturally occurring protein that is required in order to obtain the functional and structural data needed to permit one to produce a "BMP-11" protein which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are

more likely to work than not without actually making and testing them then the instant application does not support the breadth of the claims. In the instant case, the instant specification does not provide the guidance needed to predictably alter that sequence with any reasonable expectation that the resulting protein will function as an "BMP-11" or have BMP-11 activity in an osteoinduction assay. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Ngo (cited by Applicants) page 433, full paragraph 1, and page 492, full paragraph 2.

In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for "increases" or "decreases" the proliferation of neuronal cells cannot be found in the disclosure, as originally filed, which raises the issue of new matter.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 14, 2005